

Animal and Plant Health Inspection Service, USDA

§ 113.2

- 113.109 *Clostridium Sordellii* Bacterin-Toxoid.
- 113.110 *Clostridium Botulinum* Type C Bacterin-Toxoid.
- 113.111 *Clostridium Perfringens* Type C Toxoid and Bacterin-Toxoid.
- 113.112 *Clostridium Perfringens* Type D Toxoid and Bacterin-Toxoid.
- 113.113 Autogenous biologics.
- 113.114 Tetanus Toxoid.
- 113.115 *Staphylococcus Aureus* Bacterin-Toxoid.
- 113.116 *Pasteurella Multocida* Bacterin, Avian Isolate, Type 4.
- 113.117 *Pasteurella Multocida* Bacterin, Avian Isolate, Type 1.
- 113.118 *Pasteurella Multocida* Bacterin, Avian Isolate, Type 3.
- 113.119 *Erysipelothrix* Rhusiopathiae Bacterin.
- 113.120 *Salmonella Typhimurium* Bacterin.
- 113.121 *Pasteurella Multocida* Bacterin.
- 113.122 *Salmonella Choleraesuis* Bacterin.
- 113.123 *Salmonella Dublin* Bacterin.
- 113.306 Canine Distemper Vaccine.
- 113.308 Encephalomyelitis Vaccine, Venezuelan.
- 113.309 Bovine Parainfluenza₃ Vaccine.
- 113.310 Bovine Rhinotracheitis Vaccine.
- 113.311 Bovine Virus Diarrhea Vaccine.
- 113.312 Rabies Vaccine, Live Virus.
- 113.313 Measles Vaccine.
- 113.314 Feline Calicivirus Vaccine.
- 113.315 Feline Rhinotracheitis Vaccine.
- 113.316 Canine Parainfluenza Vaccine.
- 113.317 Parvovirus Vaccine (Canine).
- 113.318 Pseudorabies Vaccine.
- 113.319–113.324 [Reserved]
- 113.325 Avian Encephalomyelitis Vaccine.
- 113.326 Avian Pox Vaccine.
- 113.327 Bronchitis Vaccine.
- 113.328 Fowl Laryngotracheitis Vaccine.
- 113.329 Newcastle Disease Vaccine.
- 113.330 Marek's Disease Vaccines.
- 113.331 Bursal Disease Vaccine.
- 113.332 Tenosynovitis Vaccine.

DIAGNOSTICS AND REAGENTS

- 113.400–113.405 [Reserved]
- 113.406 Tuberculin, Intradermic.
- 113.407 Pullorum antigen.
- 113.408 Avian mycoplasma antigen.
- 113.409 Tuberculin—PPD Bovis, Intradermic.

ANTIBODY PRODUCTS

- 113.450 General requirements for antibody products.
- 113.451 Tetanus Antitoxin.
- 113.452 *Erysipelothrix Rhusiopathiae* Antibody.
- 113.453 [Reserved]
- 113.454 *Clostridium Perfringens* Type C Antitoxin.
- 113.455 *Clostridium Perfringens* Type D Antitoxin.
- 113.456–113.498 [Reserved]
- 113.499 Products for treatment of failure of passive transfer.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 34 FR 18004, Nov. 7, 1969, unless otherwise noted.

APPLICABILITY

§ 113.1 Compliance.

The regulations in this part apply to each serial or subserial of a licensed biological product manufactured in a licensed establishment and to each serial or subserial of a biological product in each shipment imported for distribution and sale.

§ 113.2 Testing aids.

To better ensure consistent and reproducible test results when Standard

KILLED VIRUS VACCINES

- 113.200 General requirements for killed virus vaccines.
- 113.201 Canine Distemper Vaccine, Killed Virus.
- 113.202 Canine Hepatitis and Canine Adenovirus Type 2 Vaccine, Killed Virus.
- 113.203 Feline Panleukopenia Vaccine, Killed Virus.
- 113.204 Mink Enteritis Vaccine, Killed Virus.
- 113.205 Newcastle Disease Vaccine, Killed Virus.
- 113.206 Wart Vaccine, Killed Virus.
- 113.207 Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus.
- 113.208 Avian Encephalomyelitis Vaccine, Killed Virus.
- 113.209 Rabies Vaccine, Killed Virus.
- 113.210 Feline Calicivirus Vaccine, Killed Virus.
- 113.211 Feline Rhinotracheitis Vaccine, Killed Virus.
- 113.212 Bursal Disease Vaccine, Killed Virus.
- 113.213 Pseudorabies Vaccine, Killed Virus.
- 113.214 Parvovirus Vaccine, Killed Virus (Canine).
- 113.215 Bovine Virus Diarrhea Vaccine, Killed Virus.
- 113.216 Bovine Rhinotracheitis Vaccine, Killed Virus.

LIVE VIRUS VACCINES

- 113.300 General requirements for live virus vaccines.
- 113.301 Ovine Ecthyma Vaccine.
- 113.302 Distemper Vaccine—Mink.
- 113.303 Bluetongue Vaccine.
- 113.304 Feline Panleukopenia Vaccine.
- 113.305 Canine Hepatitis and Canine Adenovirus Type 2 Vaccine.

Requirement tests prescribed in the regulations are conducted, National Veterinary Services Laboratories, U.S. Department of Agriculture, may provide testing aids, when available, to licensees, permittees, and applicants for licenses and permits. Such aids shall be as follows:

(a) Supplemental Assay Method (SAM) is a technical bulletin containing detailed instructions for conducting a test. Such instructions shall be in accordance with the procedures currently being followed at National Veterinary Services Laboratories and as improved, proven procedures are developed, shall be revised and reissued prior to application.

(b) Standard Reference Preparation is a serum, virus, bacterial culture, or antigen to be used in test systems for direct comparison with serials of biological products under test.

(c) Standard Test Reagent is a serum, antitoxin, fluorescent antibody conjugate, toxin, virus, bacterial cultural, or antigen to be used in test systems but not for direct comparison with serials of biological products under test.

(d) Seed cultures are small quantities of standard organisms to be propagated by the recipient to establish a supply for use.

(e) Test Code Number is a number assigned by Animal and Plant Health Inspection Service to each test procedure specified in the Standard Requirements and in each filed Outline of Production where such test is conducted to support a request for release of a serial or subserial.

[39 FR 21041, June 18, 1974, as amended at 40 FR 758, Jan. 3, 1975; 50 FR 21799, May 29, 1985; 56 FR 66784, Dec. 26, 1991]

§ 113.3 Sampling of biological products.

Each licensee and permittee shall furnish representative samples of each serial or subserial of a biological product manufactured in the United States or imported into the United States as prescribed in this section. Additional samples may be purchased in the open market by a Animal and Plant Health Inspection Service representative.

(a) Either an employee of the Department of Agriculture, of the licensee, or of the permittee, as designated by the

Administrator shall select prerelease samples of biological product in the number prescribed in paragraph (b) of this section. Each sample shall be marked for identification by the person making the selection after which they shall be packaged by the licensee or permittee, as the case may be, and forwarded to National Veterinary Services Laboratories; except that an employee of the Department may forward or deliver the samples to National Veterinary Services Laboratories if such action deemed advisable by the Administrator.

(1) Selection shall be made as follows:

(i) Nonviable liquid biological products—either bulk or final container samples of completed product shall be selected for purity, safety, or potency tests. Biological product in final container shall be selected to test for viable bacteria and fungi.

(ii) Viable liquid biological products; samples shall be in final containers and shall be randomly selected at the end of the filling operation. Bulk containers of completed product may be sampled when authorized by the Administrator.

(iii) Desiccated biological products; samples shall be in final containers and shall be randomly selected if desiccated in the final container. Biological products desiccated in bulk shall be sampled at the end of the filling operation.

(iv) Representative samples of each serial or subserial in each shipment of imported biological products shall be selected.

(2) Comparable samples shall be used by Animal and Plant Health Inspection Service, the licensee, and the permittee for similar tests.

(3) When bulk samples of completed product in liquid form are to be tested as prescribed in paragraph (a)(1) of this section, the number of such samples from each serial and the minimum quantity of product to be provided in each sample shall be stated in the filed Outline of Production.

(b) Unless otherwise prescribed by the Administrator, the number of final container samples to be selected from each serial and subserial shall be:

(1) *Vaccines*: